



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1446]

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use; Draft Guidance for Industry and Food and Drug Administration Staff; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to May 7, 2014, the comment period for the notice that appeared in the Federal Register of January 7, 2014 (79 FR 829). In the notice, FDA requested comments on the draft guidance document entitled “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.” The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance entitled “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.” Submit either electronic or written comments by May 7, 2014.

ADDRESSES: Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1601, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Patricia Bernhardt, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5654, Silver Spring, MD 20993-0002, 301-796-6136.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 7, 2014 (79 FR 829), FDA published a notice announcing the availability of the draft guidance entitled “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.” Interested persons were invited to submit comments by April 7, 2014. At this time the Agency is extending the comment period until May 7, 2014, to continue to receive public comments. Comments submitted to the docket will assist in identifying issues to be addressed in the finalized guidance document.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-07899 Filed 04/08/2014 at 8:45 am; Publication Date: 04/09/2014]